## REMARKS

Applicant thanks Examiner Stewart for the interview with Applicant's representative, Ralph Trementozzi on February 9, 2006. The substance of that interview follows.

Claims 1-37 were previously pending in the application of which claims 7, 8, 10-13, and 17-37 had been withdrawn from consideration. Claims 1-6, and 9-16 are amended herein. New claims 38-43 are added. Claims 17-37 have been cancelled. Applicants reserve the right to file a continuing application or take such other appropriate action as deemed necessary to protect the invention of these claims. Applicant do not hereby abandon or waive any rights in the invention in these cancelled claims. No new matter is being added by way of these amendments. After entry of this amendment, claims 1-16 and 38-43 will remain pending.

Claim Amendments

Claim 1 has been amended pursuant to the Examiner's suggestion during an interview on February 9, 2006. Claim 1 is amended herein to recite an additional limitation that an atraumatic element is "releasably" coupled to the distal end of the catheter. Also, claim 1 recites the additional limitation that the atraumatic element is releasable within the intestines after facilitating passage of the catheter therein and the atrumatic element is external to the catheter during passage through the intestines.

Claim 3 is amended herein similar to claim 86 recently allowed in related application serial no. 10/339,786 (the '786 application) with the addition of "an atraumatic element." Applicants' believe this amendment corrects the minor informalities identified within the Office Action. Applicants also note at least one difference between amended claim 3 and claim 146 of the '786 application in the additional limitation that "the atraumatic element [is] releasably held to the inner sheath." Additionally, the term "spherical shaped" is replaced with "atraumatic." Support for this amendment is found, for example, within the originally-filed specification at page 32, lines 3-6.

Claims 4-6, 14 and 16 are amended herein for consistency with amended claim 3.

Claims 5, 6, 11, 16 are amended herein to correct minor informalities.

Claims 3, 9-13, 15 and 16 are amended herein replacing the term "spherical shape" element with "atraumatic element." Support for this amendment is found, for example, within the originally-filed specification at page 38, lines 22-23.

Claims 17-37 are herein, cancelled.

New claims 38-43 are added herein by amendment. Support for new claims 39-40 and 42-43 is found, for example, within the originally-filed specification at page 38, lines 22-23. Support for new claims 38 and 41 is found, for example, within the originally-filed specification at page 37, lines 5-7.

Allowable Subject Matter

As an initial matter, Applicants thank the Examiner for the indication of allowable subject matter. As described below in more detail, claim 3 is amended herein to overcome the rejections under 35 U.S.C. § 112, second paragraph.

Applicants respectfully submit that after entry of this amendment, claim 3 together with claims 4-6, 9 and 14-16, which depend either directly or indirectly from claim 3, are in condition for allowance.

Anticipated Rejoinder of Claims Pursuant to M.P.E.P. § 821.04

The Examiner has required restriction to one of five identified inventions, with additional requirement for the election of species and subspecies. Applicants have elected to prosecute the claims of Group I (claims 1-16), species I (referring to Figs. 42A-42B and 43, corresponding to claims 1-16), and subspecies A (referring to Fig. 46, corresponding to claims 1-6, 9, and 14-16). Non-elected Group I claims 7, 8, and 10-13 are dependent apparatus claims depend from elected base claim 3.

As previously acknowledged by the Examiner:

> Upon the allowance of a generic claim, application will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.

Official Action, mailed from the United States Patent and Trademark Office on October 5, 2005, page 4, last paragraph.

Further, according to M.P.E.P. § 821.04:

> The propriety of a restriction requirement should be reconsidered when all the claims directed to the elected invention are in condition for allowance, and the nonelected invention(s) should be considered for rejoinder. Rejoinder involves withdrawal of a restriction requirement between an allowable elected invention and a nonelected invention and examination of the formerly nonelected invention on the merits. ... to be eligible for rejoinder, a claim to a nonelected invention must depend from or otherwise require all the limitations of an allowable claim.

As claims 7, 8 and 10-13 directed to a nonelected invention depend directly from previously-elected base claim 3, they also include all of the limitations of claim 3. As argued below, previously-elected claims 1-6, 9, and 14-16 and new claims 38-43 as amended herein are believed to be in condition for allowance. Thus, in accordance with M.P.E.P. §821.04, when all the claims directed to the elected invention are found to be allowable, dependent claims 7, 8 and 10-13 should also be rejoined and examined.

Accordingly, Applicants respectfully request that claims 7, 8 and 10-13 be rejoined and examined.

Claim Rejections Under 35 U.S.C. § 112

Claims 3-6, 9 and 14-16 stand rejected under 35 U.S.C. § 112, second paragraph. Base claim 3 is currently amended to correct certain informalities.

The Office Action also states that "the Examiner is not clear if line 12 of claim 3 is properly written." The Office Action also states that:

> the Examiner believes that the release mechanism should release the gastrointestinal implant device instead of the anchoring device, because the anchoring device is part of the gastrointestinal implant and is not an independent structure.

Currently-amended claim 3 recites, "an outer sheath ... storing a proximal portion of the gastrointestinal implant device ... the proximal portion of the gastrointestinal implant device including an anchoring device." As further recited in claim 3, "a moveable element [is provided] to secure a distal end of a sleeve ... to the inner sheath," with the "sleeve [being] coupled to the anchoring device."

Thus, the implant device includes a sleeve coupled to an anchoring device, with the anchoring device stored within the outer sheath of the delivery system and the distal end of the

sleeve secured to the inner sheath. The "release mechanism" releases the anchoring device from the outer sheath; whereas, the "sleeve release mechanism" releases the distal end of the sleeve. Contrary to the Examiner's stated belief, releasing only the anchoring device would not release the *entire* implant device as long as the sleeve remains secured at its distal end to the inner sheath.

Applicants respectfully submit that base claim 3 as amended herein is now in condition for allowance.

Claims 4-6, 9 and 14-16 depend from claim 3 and therefore include all of the limitations of claim 3. Applicants respectfully submit that claims 4-6, 9 and 14-16 as amended herein are also in condition for allowance for the same reasons.

Claim Rejections Under 35 U.S.C. § 102

Claims 1 and 2 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the Jones *et al.* reference.

The present invention relates to systems and methods for placing a gastrointestinal implant within a body. In particular, a delivery device for placing an implant includes a catheter for passage into the intestines. To facilitate navigation of the delivery device to and in the intestines, and as recited in claim 1, an "atraumatic element [is] releasably coupled to a distal tip of the catheter therein." As also recited in claim 1, the atraumatic element is "releasable within the intestines, after facilitating passage of the catheter therein. Thus, the atraumatic element can be released from the catheter within the intestines, after the catheter has been suitably positioned therein. Finally, the autramatic element is "external to the catheter during passage within the intestines."

Turning briefly to United States Patent No. 6,428,558 to Jones *et al.* (Jones *et al.*) identified within the Office Action, the reference describes an aneurysm embolization device deployment system. The system includes a catheter 4 and an embolization device 12. See Figs. 1 and 5. The embolization device includes a number of arcuate support struts connected to each other to form a substantially ellipsoidal structure. A mesh sleeve is disposed over and attached to the struts.

The embolization device 12 is described as being "radially compressed into a more ellipsoidal shape before being disposed within the distal end 8 of the catheter 4." Col. 3, ll. 54-56. See also Figs. 1 and 5. The Jones *et al.* reference further describes that the "catheter 4 is *then* inserted within a blood vessel 28." *Id.*, ll. 57-58 (emphasis added). Thus, the device 12 is disposed within the catheter during the catheter's insertion within a blood vessel. When the catheter reaches a point of deployment, "the embolization device 12 is slidingly deployed from within the distal end 8 of the catheter 4." *Id.*, ll. 58-59. See also Fig. 6. A pusher mechanism 14 is described as being used to deploy the embolization device 12 by "pushing it out the distal end 8 of the catheter 4." *Id.*, ll. 60-62.

The Office Action states that "Jones *et al.* discloses a delivery system comprising a catheter (2) and a spherically shaped element (12) coupled to the distal end of the catheter." The Office Action also states in reference to Figs. 1-6, that the Jones *et al.* reference "element is remotely releasable."

Claim 1 is amended herein to further distinguish the Jones *et al.* reference by reciting that "an atraumatic element releasably coupled to a distal tip of the catheter" and that the atraumatic element is "releasable within the intestines after facilitating passage of the catheter therein." Also, the atraumatic element is "external to the catheter during passage through the intestines." Thus, the atraumatic element is coupled to the distal tip of the catheter to facilitate passage of the catheter through the intestines. Further, the atraumatic element is external to the catheter during passage through the intestines. In contradistinction, the Jones *et al.* describes that the embolization device 12 is first "disposed within the distal end 8 of the catheter 4 ... the catheter then [being] inserted within a blood vessel." Thus, during insertion, the element 12 is disposed within the catheter, not external to the catheter and it cannot facilitate passage of the catheter. Only after reaching a point of deployment does the Jones *et al.* reference describe that the device 12 is slidingly deployed from within the distal end of the catheter. In fact, a pusher mechanism 14 is described as "pushing [the device 12] out the distal end 8 of the catheter 4." The Jones et al. reference fails to teach or suggest "an atraumatic element releasably coupled to a distal tip of the catheter" that is "releasable within the intestines after facilitating passage of the catheter therein."

Thus, the Jones *et al.* reference fails to anticipate claim 1 as amended herein at least because the reference fails to teach each and every limitation recited in amended claim 1. Although the Jones *et al.* reference does describe the device 12 as being disposed within the catheter (see Figs. 1 and 5), the reference fails to teach or suggest that the device 12 is "releasably coupled to a distal tip of the catheter" as claimed.

Moreover, the Jones *et al.* reference also describes that the device is pushed out the distal end of the catheter "when the catheter reaches a point of deployment." Thus, during insertion of the catheter within a blood vessel, the device 12 is disposed *within* the catheter. Because the device 12 is disposed within the catheter during its insertion into a blood vessel, the device 12 cannot facilitate passage of the catheter therein, as also claimed.

Applicants respectfully submit that for at least the above reasons, the Jones *et al.* reference fails to anticipate claim 1 as amended herein.

Claim 2 depends from base claim 1 and therefore includes all of the limitations of claim 1. Accordingly, claim 2 is allowable for the same reasons as argued above with respect to claim 1.

Patentability of New Claims

Claims 38-40 added herein by amendment depend either directly or indirectly from amended base claim 1. Accordingly, new claims 38-40 include all of the limitations of amended claim 1 and are allowable for the same reasons argued above.

Claims 41-43 added herein by amendment depend either directly or indirectly from amended base claim 3. Accordingly, new claims 41-43 include all of the limitations of amended claim 3 and are allowable for the same reasons argued above.

Information Disclosure Statement

An Information Disclosure Statement (IDS) is being filed concurrently herewith. Entry of the IDS is respectfully requested.

## CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By _____

Sumedha A. Bahri
Registration No. 57,427
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

Concord, MA 01742-9133
Dated: 03/01/06